

REMARKS/ARGUMENTS

Applicants have amended claim 6 to correct the misspelling of "glycine". Claims 7 and 8 have been canceled. Claims 1-6 and 11-14 will be pending after the amendments have been entered.

Rejection under 35 U.S.C. 102:

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Albert et al. (WO 97/01579) and claims 1-3, 7-8 and 11-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Albert et al. (WO 02/10192). Applicants respectfully traverse.

Claims 7 and 8 have been canceled. Therefore, Applicants respectfully request that the 35 U.S.C. 102(e) rejection be withdrawn regarding claims 7 and 8. Regarding the 35 U.S.C. 102(b) rejection of claim 1 and the 35 U.S.C. 102(e) rejection of claims 1-3 and 11-12, neither case discloses tartaric acid and therefore neither case anticipates the present claims. See MPEP § 2131. Accordingly, because neither case identically describes or discloses tartaric acid Applicants respectfully request that the 35 102(b) rejection of claim 1 and the 35 U.S.C. 102(e) rejection of claims 1-3 and 11-12 be reconsidered and withdrawn.

Rejection under 35 U.S.C. 103:

Claims 1-5 and 7-8 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albert et al. (WO 02/10192) in further view of Kamber B (US Patent # 4603120). Also, claims 1-3, 7-8 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albert et al. (WO 02/10192) in view of Stalla et al. (European Journal of Endocrinology, 1994, 130: 125-131). Further, Claims 1 and 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albert et al. (WO 02/10192) in view of Kamber B (US Patent # 4603120) in view further view of Bodmer et al. (US Patent # 5639480). Applicants respectfully traverse.

Claims 7 and 8 have been canceled. Therefore Applicants respectfully request that the 35 U.S.C. 103 rejections be withdrawn regarding claims 7 and 8.

Regarding claims 1-6 and 11-14, the tartaric acid is the key advantage of the subcutaneous formulation (and differentiates the present invention from the cited prior art). Other buffer systems in subcutaneous formulations result in irritation of the skin at the site of injection. This problem can be resolved by the use of tartaric acid (page 3, 4 bridging paragraph of the specification). Also, the tartatic acid stabilizes the formulation.

The present invention provides stable and highly tolerable formulations of compounds of formula II. The cited prior art documents contemplate the parenteral application of cyclic somatostatin analogues for similar diseases, but none of the documents mentions the problem of pain during intravenous or subcutaneous injection, neither is mentioning the lack of stability of pharmaceutical compositions comprising compounds of formula II.

The cited prior art documents do not suggest or teach the addition of tartrate to the injection composition.

Accordingly, Applicants respectfully request that the 35 U.S.C. 103 rejections of claims 1-6, 11-14 be reconsidered and withdrawn.

Applicants respectfully submit that the present claims are in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

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